Exhibit A

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

E. EDWARD KAVANAUGH
PRESIDENT

COMMENTS

BY

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

ON

THE FOOD AND DRUG ADMINISTRATION'S

PROPOSED REGULATIONS ON OVER-THE-COUNTER DRUG LABELING

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INTRODUCTION

The following comments are submitted on behalf of The Cosmetic, Toiletry, ar Fragrance Association (CTFA) in response to the proposed regulation affecting th content and format of labeling for Over-The-Counter (OTC) drugs, published at 62 *Fed. **Reg.*** 9024 (February 27, 1997) ("the proposal").

CTFA is the 103 year-old national trade association representing the personal car products industry. Our membership includes approximately 300 active member companies that manufacture or distribute personal care products, including a wide array of products that are both cosmetics and drugs, throughout the United States and, in many cases, throughout the world. We also represent approximately 300 additional associate members who provide goods and services to manufacturers and distributors of personal care products.

Although many of the products of CTFA members are regulated solely as cosmetics and are not affected by this proposal, a very significant number of our members' products are regulated both as cosmetics and as drugs. These products, referred to as "cosmetic-drugs" in this document, claim and provide both a cosmetic and a drug benefit. Both such benefits are highly valued by consumers. Products within this category would include, but are not limited to (1) antidandruff shampoos, (2) antiperspirant/deodorants, (3) anticaries toothpastes, **(4)** antimicrobial soaps, **(5)** sunscreens, ***(6)***traditional cosmetic skin-care products containing acne medicines, and (7) traditional cosmetic products, skin-care products, foundations and lipsticks that contain sunscreens, skin protectants, or astringents.

For the past 25 years CTFA has actively participated in addressing both the scientific and regulatory issues involved with developing OTC monographs for all product categories that include cosmetic-drug products. For each of these rulemakings, CTFA has filed numerous written comments with FDA, focusing on many of the unique issues facing cosmetic-drug products. Once again, in this rulemaking, CTFA has been actively involved in formal and informal public hearings since first learning of FDA's plans to conduct a comprehensive overhaul of the OTC label.

In order to put CTFA's comments in perspective, it is important to understand the similarities and differences in membership and perspective on this proposed regulation between CTFA and the Nonprescription Drug Manufacturer's Association (NDMA). While many CTFA members are also members of NDMA, because they have products that raise both traditional drug and cosmetic-drug concerns, CTFA also represents a significant number of manufacturers of cosmetic-drugs, both large and small, that are not NDMA members. In addition, many joint CTFA/NDMA members look to CTFA to represent the interests of their cosmetic/drug products while relying on NDMA to handle monograph issues for traditional OTC drug products such as analgesic or cough and cold remedies.

Many CTFA members are traditional cosmetic manufacturers who now provide drug benefits in some of their cosmetic products. These products, such as acne remedies, skin protectants, antimicrobial soaps and the sunscreen products cited above, provide valuable health benefits to consumers in a variety of cosmetic products designed for daily use. While CTFA fully supports any reasonable efforts to improve OTC labels that can be shown to improve consumers' ability to use these products safely and effectively, FDA must recognize the many important differences between traditional OTC drugs and cosmetic-drug products set forth in these comments. CTFA strongly believes that such differences, when fully considered, dictate an exemption from the proposed labeling revisions for cosmetic-drug products that are not subject to dosage limitations.

We also want to note clearly at the outset that, although we focus our comments on the need for an exemption from new labeling requirements for cosmetic-drug products

without dosage limitations, we do not intend to imply by comparison that there is any question with respect to the safety of traditional OTC drugs or that current OTC drug labeling for any OTC drug product is inadequate. All OTC drug products are extraordinarily safe products that millions of consumers use daily. They are a critical part of our health care system. However, CTFA defers to NDMA and others to address the appropriateness of the proposal for labeling non-cosmetic, traditional OTC drug products.

EXECUTIVE SUMMARY

FDA states that its proposal to revise and standardize OTC drug labels is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. FDA's proposal, however, fails to consider or distinguish between OTC drug products that the Agency claims raise the safety and consumer confusion concerns addressed in the preamble to its proposed rule and cosmetic-drug products that do not raise the concerns relied upon by FDA to support the proposed labeling changes. CTFA believes that the proposal inappropriately, and perhaps unintentionally, includes a broad category of cosmetic-drug products (i.e., those cosmetic-drugs that bear no dosage limitation) that should be exempt from the proposed OTC labeling revisions and instead continue to provide mandatory and other labeling information as currently required for both cosmetics and drugs.

- **The concerns underlying FDA's proposed OTC labeling revisions are not relevant to cosmetic-drug products without dosage limitation.** Cosmetic-drug products without dosage limitation refer to personal care products that may be used by consumers on a daily, if not more frequent, basis because of the wide margin of safety associated with their use as determined by FDA. CTFA proposes that the term "dosage limitation" be defined as:

> "a set of limitations on the size, frequency, and number of doses required in the labeling of a product either pursuant to a Tentative Final or Final OTC Drug Monograph or an approved New Drug Application."

- **FDA's concerns regarding "self-diagnosis" and "self-medication" by consumers do not legitimately apply to the types of activities associated with the use of cosmetic-drug products (e.g., the daily use of an antiperspirant/deodorant or moisturizer with sunscreen).**

  - OTC cosmetic-drugs do not include products that have resulted in more potent therapies being available to consumers;
  - Cosmetic-drugs are not the subject of prescription to OTC drug switches;
  - Cosmetic-drugs do not raise the potential for significant new serious therapeutic uses in the future
  - Cosmetic-drugs are not relied upon by consumers to mitigate illness or treat conditions that may reasonably be characterized as serious health problems; and
  - Cosmetic-drugs do not raise serious misuse concerns for the elderly.

- **Cosmetic-drug products are marketed as both cosmetics and drugs and must meet the labeling requirements for both types of products.** Thus, in addition to required OTC drug labeling, cosmetic regulations require the listing of inactive ingredients as well as certain additional, non-monograph warnings for certain types of products. Manufacturers of cosmetic-drugs also often include other important consumer information on product labels. The consequences of imposing the proposed OTC labeling changes on the current labeling system for cosmetic-drug products have not been sufficiently reviewed and, contrary to FDA's intent, could severely hamper attempts to convey important information to consumers of such products.

- **There is nothing in the administrative record to support this revolutionary change in labeling requirements for cosmetic-drugs.** Further, the results of the FDA's newly designed consumer research studies will not be available for comment to CTFA members under the present notice and comment time frames.

Both of these facts raise substantial questions of whether the rulemaking is being conducted in accordance with the Administrative Procedure Act.

- **CTFA also requests that FDA develop an exemption from the proposed OTC labeling requirements for small packages.** Many OTC drugs, including cosmetic-drugs sold through a variety of different retail outlets are packaged in small sizes. As a result, a small package exemption is essential. In the absence of such an exemption, compliance will require increased package sizes and increased use of secondary packaging. The requirements could result in the elimination of some smaller and more convenient package sizes at a time when consumers are increasingly demanding them.

- **Whether addressing traditional OTC drugs or cosmetic-drug products, FDA should consider the environmental impact of its proposed OTC labeling format as well as the impact on international harmonization that will be raised by unnecessarily limiting labeling flexibility.** In the case of cosmetic-drugs, CTFA believes that the increased packaging and corresponding environmental impact that will result from having to accommodate the proposed new labeling format will not be justified by any increase in safety or effectiveness. Similarly, where imposition of new labeling requirements will not significantly improve the safe and effective use of cosmetic-drugs, the adverse impact on international harmonization that will result from having to develop distinct labels for use outside the United States is not justified.

- **CTFA strongly supports FDA's proposal for national uniformity in the labeling of OTC drug products.** OTC drugs in general and cosmetic-drugs specifically are almost universally manufactured for sale throughout the United States. FDA's authority over such products has consistently proven to be effective in protecting all consumers. A system of conflicting state laws only undermines a strong federal regulatory framework which is in the best interests of all consumers.

The following discussion addresses the concerns identified by FDA as the basis for its actions in the preamble to the proposed rule. Our comments, organized to

address each of FDA's stated concerns, establish that the concerns relied upon by FDA to support the proposed changes in OTC drug labeling do not apply to cosmetic-drug products with no dosage limitation.

DISCUSSION

I. FDA's Concerns Regarding OTC Drugs Generally Do Not Exist For Cosmetic-Drug Products That Do Not Bear A Dosage Limitation.

CTFA understands that the underlying purpose of FDA's proposed labeling requirements is to improve the ability of consumers to read and understand OTC drug product labeling so that they will be able to select appropriate products. FDA states in its proposal:

> "The agency has determined that a standardized format for OTC drug product labeling would improve legibility and understandability and enable consumers to become more familiar with the type and location of specific important labeling information thus increasing consumer knowledge about the safe and effective use of OTC products.'"

In determining the need to revise and standardize the format for OTC drug labeling, FDA has considered, among other things, "the increased use of OTC drug products in the marketplace and the changing patterns of use of these products by consumers."[2] FDA believes that "because of the changing patterns of OTC drug use, the potential for adverse reactions and misuse of OTC drug products is increasing."[3] When analyzed carefully, however, FDA's proposal identifies only a small category of products that the Agency argues will support their concerns: Rx to OTC switch medications and certain specific OTC Product Monograph categories, such as cough/cold products. Regarding the Rx to OTC switch products, FDA can ensure their proper labeling through mandatory pre-market approval requirements. For the several existing OTC Monograph categories of concern, FDA may be able to apply its proposed labeling requirements -- with necessary modifications proposed by NDMA -- to them. But imposing the same labeling changes on cosmetic-drugs is totally unjustified and, at a minimum, serves only to apply a massive and costly government solution to a non-

problem. At worst, implementation of this proposal could confuse consumers and reduce the availability of important health benefits provided by products such as those which contain sunscreens in everyday cosmetic skin care, foundation or lipstick products.

When the individual elements of changing use relied upon by **FDA** to support the proposed labeling revisions are examined in the context of cosmetic-drug products, it becomes clear that such changes bear absolutely no relevance to the use by consumers of such drug products.

A. Changing Patterns of OTC Drug Use Identified By FDA Do Not Apply To Use By Consumers of Cosmetic-Drug Products.

The "changing patterns" of OTC drug use identified by FDA include (i) the availability of many more new OTC medications (as a result of switches from prescription to OTC status and approval of new uses for already marketed products many of which are more potent drugs; (ii) the fact that consumers are becoming more actively involved in their own health care and as a result, are more likely to practice self-diagnosis and self-medication with OTC drug products; and (iii) the increased use of OTC drug products as a result of the advancing age of many consumers.[4] While these concerns may or may not be warranted with regard to some OTC drugs as discussed above, they bear no significant relationship to use by consumers of cosmetic-drugs. Indeed, there is no substantive discussion in the preamble to the proposal that reflects any concern on FDA's part over cosmetic-drugs. Certainly the entire administrative record that presently exists provides no basis for imposing these substantial labeling changes on cosmetic-drug products.

(i) Concerns About the Increased Availability Of More Potent OTC Drug Therapies Do Not Exist for Cosmetic-Drug Products.

FDA expresses its concern regarding the increased availability of more potent OTC therapies as **follows:**

In recent years, more potent drugs have been switched from prescription

> to OTC drug status (e.g., cimetidine, naproxen sodium, ketoprofen, nicotine poacrilex, nicotine transdermal system and minoxidil topical) and new uses have been approved for certain OTC drugs (e.g., acid reducer claims for several drug products, and hair growth claims for topical minoxidil). This trend of switching from prescription to OTC status is expected to increase in the future as the safety profile of many drug products becomes more established.[5]

FDA fails to consider, however, that the products identified as new to the OTC market are Rx to OTC switch products marketed pursuant to the approval of a supplement to their already approved New Drug Applications (NDAs) for Rx use. This pre-market approval mechanism gives FDA absolute authority to require appropriate labeling prior to marketing. In contrast to the therapies specifically cited by FDA, the cosmetic-drugs for which CTFA supports an exemption are not the subject of prescription to OTC switch requests, and do not raise the potential for new uses in the future. Thus, there is no justification for subjecting cosmetic-drugs without dosage limitations to new and burdensome labeling requirements that FDA argues are necessary for a limited group of OTC drugs.

Evidence of the qualitative safety and efficacy differences between the OTC drugs about which FDA expresses concern and traditional cosmetic-drug products is reflected in the dosage limitations set forth in required labeling. Although modest dosage limitations are typical for most (if not all) oral and many topical OTC drugs that are also not cosmetics, the absence of an overall dosage limitation as CTFA has defined it in section C. below for cosmetic-drugs is reflective of the inherently wide safety margins (i.e., the difference between the effective dose and a toxic dose is relatively large)[6] associated with the use of such products.' In contrast, some OTC drug products, in addition to recommending a maximum daily dose limitation, are also required to carry a warning that extended or prolonged use is not recommended. In practical terms, the risks of exceeding the "recommended dosage" associated with some categories of OTC drugs simply do not exist for cosmetic-drugs.* FDA's focus on "potent OTC drugs" that have recently become available without prescription suggests

that the agency was not thinking of a consumer's daily use of a sunscreen, antiperspirant or anti-dandruff shampoo in the context of its concern about the increased availability of OTC drugs.

There is nothing in the administrative record developed by FDA that suggests, or supports placing cosmetic-drugs within the category of "potent OTC drug therapies" that are becoming more readily available to consumers.

(ii) Concerns About Increased Consumer Practice Of Self-Diagnosis And Self-Medication Do Not Exist For Cosmetic-Drug Products.

FDA's concern that consumers are becoming more actively involved in their own health care and more likely to practice self-diagnosis and self-medication with OTC drug products is not relevant to consumer use of cosmetic-drugs. In this regard, it is important to note that cosmetic-drugs tend to be much more like cosmetics than other OTC drugs. Whereas OTC drugs are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,"[9] cosmetics are defined as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance".[10] The majority of cosmetic-drug products are primarily used for their cosmetic effects but also are categorized and regulated as drugs either because of some intended therapeutic effect, or because the label bears claims that indicate that the product is in some way "intended to affect the structure or . . . function of the body.""

Selection, purchase and use of many cosmetic-drugs is driven primarily by the cosmetic attributes (the "aesthetics") of the product. This is particularly true for "traditional" cosmetic products such as moisturizers containing sunscreens or anti-acne ingredients, but is equally true for other categories of cosmetic-drugs (e.g., sunscreens, antiperspirant/deodorants and anti-dandruff shampoos). Given the rather unique position of cosmetic-drugs within the OTC drug category, we fail to see how FDA's

concern with regard to "self-diagnosis" and "self-medication" are applicable to such activities as the daily use of an antiperspirant/deodorant or of a moisturizer containing a sunscreen.

In justifying the proposed labeling requirements, **FDA** refers to the fact that "four times as many health problems are treated by consumers with OTC drug products instead of seeing a physician, and 60 to 95 percent of all illnesses are initially treated with some form of self-care, including self-medication with OTC products."[12] The critical distinction here is that most cosmetic-drug products, with the possible exception of antidandruff shampoos and some acne products, are preventive in nature. More often than not, they are used to prevent the onset of an adverse condition, rather than to treat an "illness." CTFA assumes that in drafting the proposed labeling requirements **FDA** did not consider the need for changing the labeling of cosmetic-drug products.

Additionally, again there is nothing in the administrative record developed by **FDA** to suggest that cosmetic-drugs raise any concerns associated with self-diagnosis or self-medication by consumers.

(iii) Concerns Over Advancing Age Of Consumers Seeking More Medical Treatment Do Not Exist For Cosmetic-Drug Products.

The final category of changing patterns of OTC drug use addressed by **FDA** is the increased use of such products as a result of the advancing age of many consumers.[13] In particular, FDA *is* concerned that "poor labeling legibility" may cause elderly consumers to "select an improper dose and thus, may result in unsafe or ineffective use of the product."[14] However with regard to cosmetic-drug products with no dosage limitations, improper dosage is not a concern. The foregoing comments notwithstanding, it is important to recognize that, in contrast to some other categories of OTC drugs involving new uses of existing OTC therapies or potent prescription to OTC switch products, elderly consumers are unlikely to begin using cosmetic-drugs for the first time during their advancing years. Quite the contrary, elderly consumers have been using these products, in many cases, for almost their entire lives. Although manufacturers continue to introduce products with improved performance, the

directions for use of such products (governed by the individual OTC monographs) remain the same.

There is nothing in the administrative record developed by FDA to suggest or support that the use of cosmetic-drugs poses any risk to elderly consumers.

B. Negative Results Of Changing Patterns Of Use Do Not Exist For Cosmetic-Drug Products.

CTFA agrees with FDA that OTC drug products (no matter how "potent") are safe and effective when used as directed.[15] We also agree that "[u]sing the product as labeled can reduce the frequency of the adverse drug experiences associated with OTC products,"[16] and that improperly or unclearly labeled OTC drug products may cause consumers to "select an improper dose, and, thus, may result in unsafe or ineffective use of the product."[17] However, the administrative record of FDA's proposed rule does not provide any evidence that current cosmetic-drug labels are the source of any public health concern.

Cosmetic-drug products have an exceptional safety record -- given their widespread use by the general populace -- and consistently report a much lower incidence of serious outcomes from accidental exposure or misuse than classic OTC drugs such as the Rx to OTC switch products, analgesics, cough, cold or allergy medications.[18] It is appropriate that higher toxicity profile products have an easy to read, standardized label. Cosmetic-drug products with no dosage limitation have a long history of safe use, indicating that consumers understand when and how to use these products. Furthermore, the potential for adverse consequences from their misuse is low. CTFA is not aware of any consumer dissatisfaction with the current labeling of cosmetic-drug products. Indeed, of the reference documents which the agency cites as evidence of the need for OTC relabeling (thirteen in total) in its proposed rule, not *one* refers to a cosmetic-drug product of any description.

(i) Concerns About Increased Potential For Adverse Drug Reactions Do Not Exist For Cosmetic-Drug Products.

As previously discussed, not all OTC drugs are the same. Issues of wrong dose size or frequency do not exist for most cosmetic-drug products. Cosmetic-drug products, such as antiperspirants, dandruff shampoos, antimicrobial soaps, and sunscreens can be used without restriction (other than those general common-sense limitations such as "if condition persists consult a health professional" or "if a rash develops, stop use"). One cannot overdose on an antiperspirant or a sunscreen. The concern with regard to selection of an improper dose resulting in an adverse drug experience should not be applicable for these types of products.

Regarding FDA's concern about the possibility of increasing numbers of adverse drug interactions because of the availability of "new OTC combination drug products for multiple symptoms" and the possibility that "[c]onsumers may not be aware that a particular prescription drug that they are taking is in the same drug class as an OTC drug product that they are also taking"", we note that it is extremely unlikely that such concerns would apply to cosmetic-drug products without dosage limitation. Indeed, the example the agency cites is a person taking an OTC analgesic in combination with a prescription nonsteroidal anti-inflammatory drug. Clearly, cosmetic-drug products do not pose this kind of situational risk. Furthermore, there are few instances of common active ingredients either between or within cosmetic-drug categories. Cosmetic-drugs containing anti-acne or sunscreen ingredients are two cases where consumers may be exposed to common active ingredients within a single category of product. In the case of sunscreens, where the use of two or more cosmetic-drug products containing common active ingredients can occur (e.g., simultaneous use of a suncare beach product containing one or more sunscreen active ingredients and a moisturizer or foundation containing similar or identical ingredients), increasing dosage serves only to increase product efficacy and thus provide increased public health benefit.

As in the case of FDA's concerns about changing patterns of use, the administrative record does not suggest or support the conclusion that there is any

potential for increased adverse reactions raised by the current use of cosmetic-drug products.

(ii) Concerns About Increas d Potential For Misuse Do Not Exist For Cosmetic-Drug Products.

There is no evidence that the "changing patterns" of use of OTC drug products will have any impact on the way consumers use cosmetic-drug products. CTFA is not aware of any significant change in what has been both appropriate and responsible use by consumers of cosmetic-drug products over decades of use. Nor is there any evidence in the record to suggest that consumers do not understand or are unable to make choices regarding their uses of such products. Furthermore, because of the distinctive marketing and particular uses of typical cosmetic-drugs compared with other OTC products (especially the new, more potent OTC products cited by FDA as the basis for its concern), there is no evidence to suggest that the current labeling of cosmetic-drugs has lead. or will lead, to confusion or misunderstanding by consumers when using other categories of OTC drug products.

Likewise, nothing in the administrative record suggests that cosmetic-drug products are at any increased risk for misuse by consumers because of their current labeling format.

C. Cosmetic-Drug Products With No Dosage Limitation Should Be Exempt From the Proposed New Label Format.

Given the lack of any factual basis for changing the labeling for cosmetic-drug products, CTFA proposes that such products with no "dosage limitation" as that term is defined herein be exempted from any final rule mandating a new label format for covered OTC drug products. This will mean that all cosmetic-drug categories that meet this definition shall be required to label their products consistent with their present requirements under the applicable OTC Monograph; New Drug Application; and required cosmetic labeling. Cosmetic-drug products subject to this exemption may not

use the new OTC format set forth in the final rule.

Under CTFAs proposal, eligibility for the exemption from FDA's new labeling requirements would require that a product satisfy both parts of a two-prong test. First, the product must be a cosmetic-drug, as determined by the claims made for the product. Second, the cosmetic-drug must not have any dosage limitation. CTFA proposes to define "dosage limitation" as follows:

> "a set of limitations on the size, frequency, and number of doses required in the labeling of a product marketed either pursuant to a Tentative Final Monograph, where applicable, or Final Monograph for an OTC Drug Product Category or a specific New Drug Application approval."

Under this definition, only products that include limits in each of the specified categories (size, frequency and number of doses) would be considered to have a dosage limitation.

A limitation on size refers to a specific restriction regarding the amount of the product to be used, e.g., one tablet, two teaspoons. A general description relating to size in the directions for use would not constitute a size limitation under this definition (e.g. use a small amount, spread a thin layer).

A limitation on frequency of dose refers to a specified time period for repeated use of a product (e.g., every four hours, three times a day). It would not encompass a general direction regarding frequency of use such as "apply often, reapply as necessary".

A limitation on number of doses refers to a specific restriction on the duration of use or the time period over which a product should be used, For example, "not to exceed more than four doses in twenty-four hours" would be a limit on number of doses.

The absence of any of the specified limits for a cosmetic-drug would place that product within the scope of the exemption. Thus, for example, a cosmetic-drug with a limitation on the frequency and number of doses but not on the size of such dose, would be exempt under the definition.

FDA does not presently define the term "dosage limitation".[20] Nonetheless, in implementing the general labeling requirements of section 502 of the Food, Drug, and Cosmetic Act (in particular the requirement that drug labeling contain "adequate warnings for use" and "adequate warnings against unsafe use"), FDA defines adequate directions for use as "directions under which the layman can use a drug safely and for the purposes of which it is intended." Such directions must include specification of "quantity of dose", or "frequency of administration or application" (in practice, the actual terms describing directions for use and warnings against unsafe use are governed by the requirements of individual OTC drug monographs). Read together (e.g., "*For relief of symptoms swallow 1 tablet with water . . . Can be used up to twice daily (up to 2 tablets in 24 hours) . . . Do not take the maximum daily dosage for longer than 2 weeks continuously except under the advice and supervision of a doctor")* such directions constitute a limitation on dosage.

CTFA is proposing to define the term "dosage limitation" because it is necessary, for purposes of understanding the impact of this proposed labeling rule on cosmetic-drug products, to look beyond the particular product category directions for use, to the entirety of the product's required labeling (including warnings). In doing so, it quickly becomes apparent that a number of OTC product categories, primarily cosmetic-drug categories, mandate only general, common sense limitations, (e.g., such as "if condition persists, consult a physician" or "if a rash occurs, stop use"). No limit on overall duration for use is raised by such restrictions, however, because no significant underlying safety concerns exist. In contrast, Rx to OTC switch products and certain OTC product categories carry significant restrictions on their use. Examples of such restrictions include the following:

Warning(s)
(Reye Syndrome Warning, Allergy Warning, Alcohol Warning)
DO Not Use: *Contraindications*
Ask a Doctor Before Use
If You Have: *Preexisting conditions (not pregnancy), symptoms*
If You Are: *Drug/drug and drug/food interactions*
If You: *Combination of "If You Have" and "If You Are"*
When Using This Product: *Side effects, and what to avoid.*
(Pregnancy/Breast-Feeding Warning)

CTFA's definition of dosage limitation is intended to distinguish between products that carry substantial limitations on use such as those identified above and for which more focused warnings are appropriate, and cosmetic-drug products that have a long history of safe and effective use utilizing the existing labeling format. Indeed, FDA previously has recognized the inherent safety of products bearing dosage limitations. In the preamble to FDA's proposed GMP regulations regarding expiration dating, the agency states: "[t]he Commissioner recognizes that many human OTC drug products are safe and suitable for frequent and often prolonged use. Such products are marketed without dosage limitations..." 43 *Fed. Reg.*, 45088 (September 29, 1978).

In order to implement CTFAs request for an exemption for cosmetic-drug products with no dosage limitation, CTFA proposes the following amendments to proposed 21 C.F.R. § 201.66:

§ 201.66 Format and content requirements for Over-The-Counter (OTC) drug product labeling.

* * * * * *

(b) Definitions.

* * * * * *

(6) The term dosage limitation shall mean a set of limitations on the size, frequency, and number of doses required in the labeling of a product either pursuant to a Tentative Final Monograph, where applicable, or Final OTC Drug Monograph or an approved New Drug Application.

* * * * * *

(f) Exemptions and deferrals.

* * * * * *

(2) Any cosmetic-drug product that does not bear a dosage limitation as defined in subsection (b)(6) shall be exempt from this section and shall bear all required labeling information in an appropriately conspicuous format.

II. Sunscreen Products Provide A Compelling Example For Exempting Cosmetic-Drug Products From The OTC Drug Labeling Proposal.

Application of FDA's OTC drug labeling proposal to sunscreens exemplifies the inappropriateness of subjecting cosmetic-drug products to the proposed label revision. Sunscreen products are marketed with various intended uses including "beach" sunscreen products to protect consumers from extreme sunlight conditions and "nonbeach" ("secondary") sunscreen products for daily use to protect consumers from chronic exposure to sunlight. Examples of daily use or "secondary" sunscreens include skin care, foundation or lipstick products. Quite simply, FDA's stated reasons for the proposed labeling changes do not apply to cosmetic-drugs generally, as exemplified by all of the products within the sunscreen category:

- Concerns about the increased availability of more potent sunscreens are nonexistent.
- Concerns about increased consumer self-diagnosis and self-medication through the use of sunscreens are nonexistent.
- Concerns regarding the possibility of increased or inappropriate use of sunscreen products (other than their *under* use) by the elderly are nonexistent.
- Concerns regarding the possibility of increased adverse reactions and misuse of sunscreen products (again, other than their *under* use) are nonexistent.

Thus, the "changing patterns" of OTC drug use identified by FDA as justification for its proposal do not apply *to* sunscreens.

For the same reasons, FDA's concerns about increased consumer self-diagnosis and self-medication do not apply to sunscreens. Sunscreens are widely used by consumers and sufficiently labeled for safe and effective use under current OTC drug and cosmetic labeling requirements. To the extent their use by consumers reflects any of the changing patterns of use identified by FDA in its proposal, such changes are precisely those that FDA and public health officials are encouraging for sunscreen use. For example, to the extent sunscreen use can be characterized as self-medication by consumers or as presenting opportunities for increased use by the elderly, a wide array of public health agencies and experts openly promote such uses. Indeed, in contrast to traditional OTC drug therapies, FDA's concern with regard to sunscreens should be product ***under*** use rather than ***over*** use.

FDA's concerns regarding the possibility of increased adverse reactions and misuse of OTC drug products also do not apply to consumer use of sunscreen products. It is universally recognized that substantial exposure to the ultraviolet rays of the sun can produce a wide variety of adverse health consequences, ranging from immediate burning of the skin, to premature aging, wrinkling and other damage to the skin, to various types of skin cancers including malignant melanoma (a very serious form of skin cancer that has increased dramatically). The American Academy of Dermatology and consumer groups have expressed concern that (i) consumers do not use enough sunscreen and that (ii) many consumers do not understand the importance of protection from everyday UV exposure afforded by products such as cosmetic moisturizers containing sunscreen ingredients. In practical terms, the dangers of exceeding the "recommended dosage" associated with some categories of OTC drugs simply do not exist for sunscreens. indeed, increasing dosage serves only to increase product efficacy and provide a health benefit.

Advocates of the use of sunscreens on a routine, daily basis have increasingly urged the cosmetic and personal care industry to publicize the health importance of sunscreens and to include sunscreen ingredients not only in sunscreen products for beach use, whose primary purpose is to protect consumers from extreme sunlight

conditions (often referred to as "beach" sunscreen products), but also in large numbers of "traditional "cosmetic products. The industry has responded by supporting substantial public education efforts and by reformulating a large number of cosmetic products to include sunscreen ingredients. This response reflects a genuine industry interest in sound public health principles, and is motivated by a desire to accommodate these principles where that can be accomplished without detracting from the basic cosmetic purpose of the product itself.

In order to encourage continued efforts by industry to incorporate sunscreen ingredients (wherever feasible) in all types of skin care products, it is vital for FDA to provide a regulatory framework incorporating flexible labeling requirements. Overly rigorous or unnecessary labeling requirements may simply create a disincentive to manufacturers and even lead to the removal of sunscreen ingredients from certain daily-use products. Such an unintended consequence of the proposed labeling requirements clearly is contrary to a sound public health policy.

Finally, nowhere in the record supporting **FDA's** proposed labeling revisions is there any evidence that consumers are unable to read or understand information necessary to the safe and effective use of sunscreens where such products are properly labeled under current regulatory requirements. This lack of tangible support for FDA's proposal to enact drastic labeling changes for cosmetic-drug products clearly violates applicable **APA** requirements.

For all of the above stated reasons, CTFA firmly supports an exemption from the proposed OTC labeling regulation for sunscreen products. Such action would be consistent with the public health goal of encouraging consumers to increase their use of sunscreens and of granting an exemption for all products which are not the subject of traditional dosage limits for OTC drug products.

III. Current Mandatory And Other Labeling For Cosmetic-Drug Products Supports Their Exemption From The OTC Drug Labeling Proposal.

Cosmetic-drugs are regulated as both cosmetics and drugs and must comply

with applicable labeling requirements for both types of products.[21] As a result, cosmetic-drug products currently are required to include more mandatory labeling information than traditional OTC drug products. CTFA believes that the information provided on cosmetic-drug products under the current rules is sufficient to guarantee the safe and effective use of such products. Imposing the proposed formatting requirements on such products may very wel interfere with the provision of required information. Unlike the OTC drug products of true concern to FDA, consumers buy cosmetic-drugs for both benefits. Often the drug benefit is not the primary reason for product purchase; to force a labeling format that restricts the conveyance of important cosmetic information to consumers, absent a documented concern for the safe and effective use of the product, is absolutely unwarranted. Thus, such products should be exempted from the proposed labeling changes for OTC drug products.

A. Extensive Mandatory Cosmetic Labeling Requirements Already Exist.

Cosmetic-drug products, unlike OTC drug products that are not also cosmetics, are required to "bear a declaration of the name of each [cosmetic and/or inactive] ingredient in descending order of predominance" in addition to a declaration of the active drug ingredients.[22] For some consumers, label information on the inclusion of cosmetic/inactive ingredients in a product formulation is particularly important because they have been advised by a dermatologist or other physician that they may be allergic to one or more chemical ingredients and should therefore avoid using products which may contain them.

For many cosmetic-drug products, the list of cosmetic/inactive ingredients used in the formulation can be extensive. Furthermore, the names of individual inactive ingredients may, in many cases, be fairly lengthy. Consequently, the requirement to list inactive ingredients is a significant determinant of the residual space available for compliance with the requirements of the proposed labeling proposal. For some products, particularly those sold in small package sizes, having to comply with the proposed OTC labeling format may mean that manufacturers will be unable to list all the cosmetic/inactive ingredients on the same label panel. Consequently, consumers will have to search in more than one location on the package for important information

necessary for the safe use of the product. Since avoidance of cosmetic ingredients that may cause allergic reactions is perhaps the single most important use of required information on a cosmetic label, applying this OTC drug labeling requirement to cosmetic-drugs may negate an important benefit provided by mandatory cosmetic ingredient labeling.

Even more confusing for consumers is the proposed standardized format which would require the listing of active ingredients to be *separated* from the cosmetic/inactive ingredients by other required labeling information. Thus, in order to comply, cosmetic drug products would be required to include important information on ingredients in **two** different locations.[23] Any requirement which results in the increased possibility that a consumer may inadvertently fail to identify a particular ingredient to which he or she is likely to have an allergic reaction is contrary to public health policy and to the stated goals of FDA in promulgating the proposed labeling regulation.

In addition to listing cosmetic/inactive ingredients, some cosmetic-drugs -- those which are sold in self-pressurized containers (e.g., antiperspirant/deodorants) -- ***are*** required to bear additional warning statements (e.g., proper storage conditions; keep out of eyes; flammability; inhalation).[24] In terms of the consumer's ability to use the product safely, the aerosol warning statements for antiperspirant/deodorants sold in aerosol containers are just as important to the consumer's ability to use the product safely as those warnings required by the antiperspirant monograph.

B. Other Important Cosmetic Labeling Is Jeopardized By The Proposal.

In addition to the information required by **FDA** under both cosmetic and OTC labeling provisions, consumers currently derive much important (but not mandated) information from the labels of cosmetic-drugs. Manufacturers of cosmetic-drugs use label space to distinguish their products from similar OTC products (that do not include cosmetic claims) and to advise consumers of particular cosmetic attributes (e.g., "dermatologist-tested," **"ophthalmologist-tested,"** won't run into eyes," "safe for use with

contact lenses," "non-comedogenic," "PABA-free," "oil free," etc.) which many consumers and health professionals consider important.

Finally, some cosmetic-drug products include other important information such as direct consumer counseling regarding proper product use and storage. Continued use of "800" phone numbers may be eliminated if manufacturers cannot find adequate space on the label. Additional information of help to consumers in selecting products includes the Skin Cancer Foundation seal on sunscreens, Good Housekeeping Seal of Approval, American Dental Association endorsement from its Council on Dental Therapeutics, recycling logos, and the European "e" code.[25]

C. Cosmetic-Drugs Already Are Subject To Mandatory OTC Drug Labeling Requirements.

Currently, cosmetic drug products have numerous mandatory labeling requirements. First, there are the general OTC labeling requirements applicable to all products (21 C.F.R. § 201.1 et seq. and § 330.1 et seq.). In addition, Tentative Final Monographs, while applicable, and all Final Monographs (presently 21 C.F.R. § 331 through § 358) contain explicit labeling requirements. For those very few cosmetic-drug products approved pursuant to an NDA, that approval dictates all drug labeling requirements. All of these specific requirements must be measured against the statutory requirement that all mandatory drug information be conspicuous and ". . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[26]

The exceptional safety record of cosmetic-drug products is largely due to the fact that current cosmetic-drug product labels and accompanying labeling *are effective* in explaining their proper selection and use. Current cosmetic-drug labels provide valuable information to the consumer such as required monograph and NDA approved language. They may also, however, include some of the additional information described above. CTFA believes that the *scope* of labeling requirements and the *amount* of information currently required on a typical cosmetic-drug product is more

than sufficient to guarantee the safe and effective use of such products. The proposed labeling requirements will require consumers to look in several places on the product label for warnings, use instructions and lists of active or inactive ingredients. Contrary to FDA's intent, the proposed labeling requirements will make it *more* difficult for a consumer to select the right cosmetic-drug product to meet his or her needs and, even more importantly, to ensure safe and effective use of the product.

IV. The Requirements Of The Administrative Procedure Act Must Be Followed.

There is no factual basis in the administrative record that would warrant imposing FDA's proposed labeling change, and its attendant costs, on manufacturers of cosmetic-drug products. CTFA believes strongly that the requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 et seq., should apply both as to the adequacy of the administrative record to make changes in long-standing labeling requirements as well as to the sufficiency of the opportunity provided to affected parties to review and comment upon relevant data.

A. The Record Is Devoid Of A Factual Basis To Support The Rules The Agency Proposes.

CTFA has several substantial concerns with regard to the administrative record and process presently being utilized by FDA in this rulemaking. As thoroughly set forth above there is virtually nothing in the administrative record presently that would support application of FDA's proposal to cosmetic-drugs. In addition, on May 23, 1997, FDA published a notice requesting comments on a proposal to collect data in the form of four studies regarding consumer preferences for, and comprehension of, information contained in OTC drug labels. Given the estimated costs to relabel OTC drug products as evidenced by these comments and the comments of the NDMA, FDA's proposed consumer research is disturbing. It appears that the agency itself is uncertain about consumer understanding of information contained in OTC drug product labels. Existing data on how consumers understand current labels and whether there is an actual need

for FDA's proposed OTC labeling format has been virtually overlooked in favor of four studies -- with design flaws -- the results of which will not be published until next year, well after the public comment period on the proposed labeling rule has closed. Upon completion, these studies could lead to the development of another label format, which would be inherently unfair given that industry is already investigating the impact of the proposed labeling rule by doing label "mock-ups" and revising existing label copy.

The agency has not established the necessity of a new OTC label format -- especially for cosmetic-drug products. FDA has not cited one cosmetic-drug product that raises the same concerns about the potential for misuse as some OTC drug products. Furthermore, FDA's proposed research does not include cosmetic-drugs other than a sample sunscreen label in the new label format. This sole cosmetic-drug example is suggested as one of two types of drug products for study which considers participants' evaluation of four design variations of the proposed label format.

B. The APA Mandates That An Agency Have Factual Support In The Administrative Record For Its Substantive Rules.

Presently, there is nothing in the administrative record regarding cosmetic-drugs that would provide a lawful basis for a final rule as proposed by FDA. The APA requires that an agency provide a factual basis for the rules that it proposes. See B B & L, Inc. v. NLRB, 52 F.3d 366 (D.C. Cir. 1995) (court will not uphold agency decision that is unreasonable, arbitrary, or unsupported by the evidence); Int'l Brotherhood of Teamsters, Chauffeurs, Warehousemen and Helpers of America v. U.S., 735 F.2d 1525 (D.C.Cir. 1984) (when an agency seeks to change federal policy, the record must support that change). Agency promulgation of a rule that lacks an adequate factual basis is a clear violation of the APA.

Under the APA, reviewing courts will strike down agency actions that are arbitrary or capricious, including those for which there is no factual basis in the record. 5 U.S.C. § 706(2)(A). While the APA's scope of review under the arbitrary and

capricious standard is narrow, and the court may not substitute its judgment for that of the agency, the court will do a searching examination to determine whether the agency's decision was reasoned, i.e., whether the agency considered relevant facts and explained facts and policy concerns on which it relied, and, importantly, whether those facts have some basis in the record. Nat'l Treasury Employees Union v. Helfer, 53 F.3d 1289 (D.C. Cir. 1989). See also Marymount Hosp., Inc. v. Shalala, 19 F.3d 658 (D.C. Cir. 1994) (court may set aside agency decision where unsupported by substantial evidence in the administrative record); Center for Auto Safety v. Federal Highway Admin., 956 F.2d 309 (D.C. Cir. 1992) (agency action is arbitrary and capricious if it rests upon factual premise that is unsupported by substantial evidence).

The record in this rulemaking is totally devoid of any factual basis for the proposed rule with regard to cosmetic-drugs. Quite simply, FDA has not demonstrated a need for a new label format with regard to these products. Such a record will not withstand APA challenge.

Moreover, the factual basis for a rule must be contained in the record and provided contemporaneously with the rule for public comment. Post-hoc rationalizations to justify actions or rule changes will not withstand judicial scrutiny. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971) (court refused to accept as record the agency's post hoc rationalizations of its decisions); Carlton v. Babbitt, 900 F. Supp. 526 (D.D.C. 1995) (court may not entertain post hoc rationalizations where no rationale was set forth before). Accordingly, FDA is required to set forth an adequate factual basis for a rule in the record and before that rule is promulgated. FDA's actions in this instance are exactly backwards. The agency has issued a proposed rule for which it is now attempting to build a factual basis through consumer research. With regard to cosmetic-drugs, however, which are not the subject of such consumer research, we can only assume that because FDA's stated reasons for the regulatisn do not apply to those products, the record, in violation of the APA, will continue to lack a factual basis for the rule.

C. The APA Mandates That All Material Facts Relied Upon By FDA Must Be The Subject of Notice and Comment Rulemaking.

There is substantial consumer research yet to be done which addresses the need for, and the appropriate format of, revised OTC drug labeling. That research will not be complete until well after the October 6, 1997 close of the comment period in this rulemaking. Further, as noted above, that research does not seek information that would, in any material way, address whether such a labeling change is appropriate for cosmetic-drugs, and if so, the format such a label should take.

It is one of the most basic requirements of the APA that parties to a rulemaking be provided with notice and an opportunity to be heard. APA § 553(c). Interested parties are deprived of this most basic right when an agency fails to make available for public comment important studies and other data on which they rely in the final rule. U.S. v. Nova Scotia Food Products, 568 F.2d 240 (2d Cir. 1977) (challenge to FDA rulemaking upheld for failure to make record available which included studies relied upon by the agency). See U.S. v. Menendez, 48 F.3d 1401, 1409-10 (5th Cir. 1995) (reversing district court's judgment where decision was based on less than the whole record); Hanover Potato Products, Inc. et al. v. Sullivan, 1991 U.S. App. LEXIS 33093 (3d Cir. May 22, 1991) (court upheld challenge to FDA's final rule banning the use of sulfites on fresh potatoes where agency failed to make portions of the administrative record on which FDA relied available for notice and comment); Walter O. Boswell Memorial Hosp. v. Heckler, 749 F.2d 788 (D.C. Cir. 1984) (agency must provide full record of its decision.)

The court in Hanover Potato went on to state that "[b]oth the [APA] and the [FDA] regulations provide the public with the opportunity to review, comment upon, and if appropriate challenge the evidentiary basis for a proposed agency rule. To fail to provide the public with access to the underlying information is to defeat the very purpose of the prescribed procedure." See Louisiana Ass'n of Independent Producers

and Royalty Owners v. FERC, 958 F.2d 1101 (D.C. Cir. 1992) (interested parties must have the opportunity to introduce adverse evidence and criticize evidence introduced by others). Moreover, the notice-and-comment procedures serve the additional purposes of allowing the agency to benefit from the experience and input of the parties who file comments and to educate the agency, thereby helping to ensure informed agency decision making. Chocolate Mfrs. Ass'n v. Block, 755 F.2d 1098 (4th Cir. 1985) (citations omitted). Because FDA's consumer research will not be completed until after the close of the comment period -- and, in any event is unlikely to contain information relevant to cosmetic-drugs --the agency, in violation of the APA, is depriving interested parties of the opportunity to review or comment on the substantive basis for its proposal in any meaningful way.

V. A Categorical Small Package Exemption Is Essential.

By these comments, CTFA requests a small package exemption to provide relief for small packages which cannot comply with the currently proposed labeling changes. Attempting to meet all the labeling requirements for a cosmetic and an OTC drug in a limited label space is a complex problem. A "one-size fits all" approach which treats cosmetic-drugs and other OTC drugs alike may not be either an optimal or workable solution. For those cosmetic-drugs that would not meet the dosage limitation criteria for exemption from the proposed labeling changes, a small package exemption is essential. Such an exemption would mean that small packages subject to the proposed rule would have to comply with all present OTC drug labeling requirements.

Unlike the majority of OTC drugs, cosmetic-drug products are much more likely to come in a wide array of package shapes and sizes. Potential compliance problems for products typically packaged in small sizes are exemplified by many cosmetic-drugs (especially traditional cosmetic products containing sunscreens, e.g., lipsticks, lip balms, concealers, foundations, or traditional cosmetic vehicles containing antiacne ingredients, etc.). For many such products it is important to understand that it is not just package size but a combination of both size and shape which determine the amount of available label space on a given package. Packages which are particularly affected are

bottles without an outer carton, tubes, specialty shaped containers, and convenience sizes.

CTFA strongly supports an objective standard for determining whether a particular package is eligible for a small package exemption. Relying on a subjective standard to support an exemption from the proposed labeling format would be both inefficient and unfair. Under a subjective system manufacturers of many cosmetic-drug products would be required to maintain records of attempts to comply with the labeling requirements; and the adequacy of such attempts could be subject to different standards by different field inspectors. In contrast, an objective standard will provide a clear formula for manufacturers to follow, conserving resources and ensuring consistent, agency-wide treatment of products.

A. The Limits On Available Label Space And The Importance Of Cosmetic Claims Necessitate A Small Package Exemption.

FDA itself has recognized that cosmetic claims are permissible on the label of a cosmetic-drug product if they are placed "somewhere else in the labeling" of the product.[27] Indeed, the agency has recognized that "OTC drug monographs contain appropriate drug labeling claims to be used on OTC drug products and do not preclude the use of acceptable cosmetic claims if the product is both a drug and cosmetic."[28]

The agency has also stated that "any term that is outside the scope of the monograph, even though it is truthful and not misleading, may not appear in any portion of the labeling required by the monograph" but such terms may appear "elsewhere in the labeling provided they are not false or misleading."[29] CTFA has consistently expressed its opposition to this so-called "label separation" policy and reiterates that opposition again here. Nevertheless, this difference aside, it is apparent that FDA acknowledges that cosmetic claims on a cosmetic-drug product are appropriate and necessary for a consumer to make an informed and prudent choice of product.

For these reasons, any evaluation of total surface area available for labeling on the back and side panels -- for purposes of a small package exemption -- must include

a certain percentage of available space for required cosmetic labeling, cosmetic claims and other essential, but non-OTC drug information. In order to accommodate the multiplicity of cosmetic-drug product labels in terms of number of ingredients and individual OTC monograph or NDA mandated language requirements, we propose a small package exemption based on available label space, i.e., where (i) the total surface area available to bear labeling is less than 12 square inches (including the principal display panel); or (ii) more than 60% of the total surface area available for labeling on the back and side panels, if any, (excluding the principal display panel) must be used to satisfy the "content requirements" as described in proposed section 201.66(c); or (iii) it is a trial size package, packette, or single use unit.

B. The Citizen Petition Procedure Is Unrealistic For Industry And FDA.

In the absence of CTFA's proposed small package exemption, the Citizen Petition procedure currently envisioned under the proposed rule (i.e., by which manufacturers of products would apply to FDA for an exemption on a product-by-product basis) would be extraordinarily burdensome for FDA and unrealistic for purposes of providing any genuine relief to manufacturers of cosmetic-drug products. As FDA well knows, the Citizen Petition process is a lengthy one that places on FDA no obligation to provide a final, substantive response in any specific time frame. FDA's procedural regulations (21 C.F.R. § 10.30) contemplate a response within 180 days. FDA has publicly stated repeatedly that it is not bound by this time frame and that it will grant itself an unlimited extension of time if it deems it appropriate. FDA receives a substantial number of Citizen Petitions in a year and CTFA believes that the overwhelming majority are not answered in a substantive manner either in 180 days or in several years for that matter.

In addition, the cosmetic-drug industry is launch-intensive. Often multiple launches of new cosmetic-drug products occur six months apart. A manufacturer may launch two or three "color stories" annually, with dozens of new lipstick shades, each

containing sunscreen. This differs from the classic OTC product area where products such as analgesics and pain relievers have long incubation times and remain in the market for many years. Given the time frames associated with FDA's petition review procedures, it is highly unlikely that companies would be willing or able to avail themselves of the proposed option. It is more likely that manufacturers would decide to eliminate the therapeutic benefits from many of their traditional cosmetic products (e.g., by eliminating the use of sunscreens in cosmetics such as lipsticks and foundations), to the detriment of the public health.

The practical result of FDA proposing a Citizen Petition approach to seeking an exemption is to propose effectively that there be no exemptions in any useful time frame. As a result, a categorical small package exemption is critical.

C. Performance Standards Do Not Exist; Nor Are They A Practical Solution

FDA has called for comment on the use of performance standards as a way to address the problems presented by small packages. CTFA agrees with NDMA that there are no validated performance standards that would apply and therefore they should not be further considered by FDA. Rather, CTFA is providing an explicit, workable framework for how small packages should be labeled. FDA should adopt the CTFA proposal contained herein.

Obviously, if FDA rejects both the CTFA and NDMA positions on this matter, the APA would require that prior to imposing any Performance Standards they be the subject of notice and comment rulemaking.

D. CTFA Proposal Would Provide A Cosmetic-Drug Small Package Exemption.

In order to implement CTFA's proposal for a small package exemption, CTFA proposes the following amendments to 21 C.F.R. § 201.66:

§ 201.66 Format and content requirements for Over-The-Counter (OTC) drug product labeling.

* * * * * *

(b) Definitions.

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(7) A small package means any outer package:

(i) if the total surface area available to bear labeling is less than 12 square inches (including the principal display panel); or

(ii) if more than 60% of its total surface area available for labeling on the back and side panels, if any, (excluding the principal display panel) must be used to satisfy the "content requirements" as described in proposed section 201.66(c); or

(iii) that is a trial size package, packette, or single use unit.

* * * * * *

(f) Exemptions and Deferrals.

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(3) Any cosmetic-drug product that is contained in a small package as defined in subsection (b)(7) shall be exempt from this section and shall bear all required labeling in an appropriately conspicuous format.

VI. There Are Several Additional Factors Which Justify Both An Exemption For Cosmetic-Drugs With No Dosage Limitation And A Small Package Exemption Generally.

In considering how cosmetic-drug products should be labeled, there are several additional factors that FDA must consider. These factors include consumer expectations as to the products they are purchasing and consumer demand for, and

access to, a variety of package sizes for products. In addition, as with every rule mandated by **FDA,** there are always potential unintended consequences. With regard to this rulemaking, the potential for increased packaging to comply with the proposed requirements raises environmental issues of significant concern. At the other end of the governmental spectrum, any change in labeling for these safe and effective products must be evaluated against the compelling value in an increasingly global marketplace and the need to harmonize labeling requirements. This is an extremely important factor in preserving the ability of U.S. companies to compete throughout the world. In considering all of these factors, it is clear that a change in labeling requirements without a compelling factual need fundamentally disrupts a complex marketing system and related regulatory requirements without any significant benefit from such changes.

A. The Diversity Of Marketing Channels And Packaging Sizes Is Significantly Different For Cosmetic-Drug Products Than For Traditional OTC Drugs.

(i) The Fact That Cosmetic-Drugs Are Sold In Department And Specialty Retail Stores Impacts Their Packaging And Labeling.

Cosmetic-drug products are marketed and sold through many different channels of trade including by direct sales representatives, grocery stores, mass merchandisers, drug stores, beauty salons, direct-response television, specialty retail, and department stores.

The variety of ways in which cosmetic-drug products are sold varies significantly from other OTC drugs, **and** has an impact on how products are packaged and labeled. Importantly, such packaging and labeling reflects consumer demand and the greater or equal interest that consumers have in the cosmetic as opposed to drug benefits of such products. In today's competitive marketplace, manufacturers must market their products to meet the requirements of different conditions of trade. Cosmetic-drug manufacturers must have enormous flexibility in packaging and labeling to accommodate the respective requirements of each setting.

The requirements of packaging a cosmetic-drug product for an upscale department or specialty retail store are often very different from the requirements of packaging a cosmetic-drug product for a mass merchandiser retail location or direct access. This difference is based on functional and aesthetic reasons which go to the essence of why consumers purchase such products in different retail settings. Consumers go to department stores to buy cosmetic-drugs for very different reasons than they go to the corner grocery or convenience store to buy a cold remedy. They do not expect or want the packaging and labeling to be the same on every available product under those very distinct circumstances. The packaging of cosmetic-drug products sold in department stores is very important to create brand recognition. Trade dress -- the unique colors, type face, package size and shape -- is extremely important because it is an integral part of the overall marketing of the product. Trade dress distinguishes one brand from another and some cosmetic products have trade dress which has been in use for years. A cosmetic product's distinctive trade dress is incorporated into all product labeling and advertisements, product samples, even shelf layout plans and store displays. Cosmetic-drug products must therefore complement the trade dress and packaging of the general cosmetic line, since they are usually sold as a line extension of a cosmetic product.

Although the importance of these marketing issues may not seem obvious to FDA at first blush, they are in fact quite important to the public health issues that may be affected by this labeling proposal. Returning to our sunscreen example, it is important that sunscreens be available for daily use in as many vehicles as possible that will encourage consumer use. In order to sell product in a variety of consumer outlets, manufacturers must meet the marketing requirements of each retail environment. It is unrealistic to think that a "one-label fits all" formula for cosmetic-drugs will work in retail environments where creativity and brand-identity, as signified by distinctive trade-dress, sell products. The consumer often buys a skin-care product with sunscreen in such an environment primarily because that consumer knows and values other products in that manufacturer's product line. In many cases, the presence of sun protection is an added

benefit, not the primary incentive. Yet, it benefits the public health to encourage the consumer to purchase this product. Imposition of this labeling proposal on these products will not assist such a consumer, and it is at least equally likely that such a consumer will be put-off or confused by a complex label that differs from other products in that line and will choose a product without sunscreen.

(ii) The Requirements Of Mass Retail And Other Channels Of Commerce Impact The Manner In Which Cosmetic-Drugs Are Sold.

Another issue to consider are the requirements of the retail setting. Mass merchandisers often require cosmetic-drug manufacturers to sell their products in area display equipment designed to suit the merchandiser's space requirements. For example, many companies have recently invested in new gravity-feed display equipment to dispense color cosmetics containing sunscreens (e.g., uncartoned foundations, blushes, lipsticks). To the extent that new methods of display, marketing and sale of products dictate smaller packaging, these factors should be considered by **FDA.**

In all channels of trade for cosmetic-drug products, product packaging is critical to the consumer's use of the product. Adequate space on the actual package to identify the product attributes of a cosmetic-drug product is critical since it is the primary vehicle to describe the cosmetic and drug benefits derived from using these cosmetic-drug products. It explains what the consumer can expect to see as a result of using the product.

Trial size packaging and gift-with-purchase product sizes that fit the proposed definition of a small package are integral to encouraging consumers to use and understand the benefits of cosmetic-drug products across all channels of trade as well.

Label constraints on trial samples and single use products may significantly impact the desire of consumers to select and use them, because consumers rely on label copy to explain the end benefits derived from using them.

Furthermore, many marketers offer items promotionally as part of sets, travel kits, gifts-with-purchase, and "blockbuster sets" (very large gifts-with-purchase, frequently used at holiday times.) Such sets may contain cosmetic-drug products within the mix, and if additional labeling is required, will become confusing in appearance due to their complexity, or otherwise discourage marketers from including products of this type.

B. The Proposed Regulation Raises Significant Environmental and Solid Waste Reduction Issues.

Many cosmetic-drugs are currently marketed with minimal packaging. Application of the proposed OTC labeling requirements undoubtedly would require the development of secondary packaging for many of these products in direct contradiction of attempts to preserve and protect environmental resources. Any FDA policy that dictates more packaging, without a substantial public health benefit, is contrary to the broader public interest. Thus any consideration of further package designs for cosmetic drugs is highly unwarranted. At all levels of the public and private sector, solid waste reduction or "source reduction" is at the forefront as a tool for preventing pollution. EPA has recognized the "solid waste hierarchy" which states that source reduction is the number one way to reduce solid waste.[30]

Several states -- most recently Oregon -- have followed suit by declaring that source reduction is the best way to reduce the flow of materials into the solid waste stream. Source reduction offers substantial financial benefits to taxpayers. For more than a decade source reduction has been the best way to cut the cost of trash disposal. Less trash means fewer transfer stations, landfills, incinerators and lower capital costs. This means lower taxes to pay for waste disposal. Ultimately, source reduction has a dual advantage: it cuts the flow of material and saves the consumer money.

Source reduction may be the only way many cosmetic-drug manufacturers can comply with the various state requirements to reduce solid waste and promote recycling. Federal regulations that address product safety and packaging integrity restrict the reuse and use of most post-consumer recycled materials. In FDA's March 24, 1993 letter to CTFA, which makes reference to the use of recycled materials in food packaging, FDA acknowledged the importance of product aesthetics for cosmetic "marketing standards":

> FDA recognizes that many different government bodies, both at the federal and state level, are concerned about environmental damage that may occur because of the large amount of waste material generated from consumer packaging. As you point out, several states have either enacted or are contemplating the introduction of legislation that would make the use of recycled material in product containers mandatory. . . . Cosmetic product packaging differs significantly from food packaging in that it plays an important role, not only in terms of product integrity, but also in product aesthetics. . . . The agency recognizes that development of safe and suitable packaging for the wide variety of cosmetic products marketed today is a complex and challenging endeavor. Packaging for the many different types of cosmetic products requires considerable development time and investment before a manufacturer can be sure that it will meet the legal requirements of the Act as well as aesthetic marketing standards.[31]

Retailers -- especially mass merchandisers, chain food retailers, and drug stores -- have also felt the need to reduce product packaging. As more stock keeping units (SKUs) are developed, there is more competition for shelf space. A manufacturer often puts itself at a competitive disadvantage by not reducing outer packaging which uses limited shelf space. This reduction in product packaging has resulted in significant cost savings to the manufacturer which ultimately is passed on to consumers. Examples of these cost savings include reduced costs to transport and store products.

C. The Proposed Regulation Will Adversely Affect Efforts To Achieve Harmonization With Overseas Labeling Requirements.

in order to be as competitive as possible, U.S. manufacturers are attempting to

develop uniform packaging to enable products to be sold both overseas and in the United States without costly and unnecessary packaging changes for various markets. Indeed, FDA is increasingly focused on international harmonization as a matter of agency-wide policy. Limiting flexibility in the way manufacturers are able to comply with overseas labeli g requirements (as well as the fle ibility to provide other essential information on product labels) can only lead to duplication of packaging for overseas markets. Such duplication of effort leads to increased production costs and, inevitably, increased costs to the consumer.

In Canada "drugs that are like cosmetics" (e.g., antiperspirant/deodorants, antidandruff shampoos, medicated skin creams and lotions, anticaries toothpastes and sunscreen products) are treated as "proprietary medicines" (i.e., drug products that are in a form ready for use by the consumer according to the directions for use recommended by the manufacturer[32] and do not require the advice or interaction of a health professional). As in the U.S., the labeling requirements for drugs are much more extensive than for cosmetics and include a requirement for the declaration of active ingredients, dosage recommendations, identification of possible adverse reactions and drug interactions, mandatory identification by lot number, etc[33]. Reconciliation of the specific requirements of the proposed FDA OTC labeling provisions and those required under the Canadian Food and Dru gs Act and Regulations (and therefore uniform labeling of cosmetic-drug products offered for sale in the U.S. and Canada) may not be possible and thus the FDA proposal represents a significant barrier to efforts to achieve international harmonization.

The requirement for listing of inactive ingredients, supra, is compounded by the fact that companies who wish to market the same product inside and outside the European Union must use dual labeling (i.e., list both alternatives) for certain (such as colorants, botanicals, trivial names, alcohol) ingredients that have different nomenclature in the U.S. and the European Union. Similarly, a product sold throughout Canada, must declare all label copy in both French and English, further impeding

industry's ability to comply with **U.S.** OTC labeling restrictions for small packages.

In many countries (most notably in the EU), products which in the U.S. are termed cosmetic-drugs are considered cosmetics.[34] Consequently, product labels which comply with the proposed U.S. regulations for cosmetic-drugs will appear very different from similar products produced in the host country (i.e., which would also require OTC labeling if sold in the U.S.) but which are treated like any other cosmetic product. In the marketplace for cosmetic and cosmetic drugs (i.e., where product appearance -- trade dress -- is so important), such differences in appearance may act as a disincentive to consumers who are more likely to purchase a product manufactured in the host country. Clearly, compliance with the FDA proposal for U.S. manufactured cosmetic-drug products marketed overseas is likely to be commercial disadvantage to U.S. manufacturers and a barrier to trade.

VII. National Uniformity In The Labeling Of OTC Drug Products Is Essential.

CTFA strongly supports FDA's proposed regulation to ensure national uniformity in the labeling of OTC drug products. Proposed 21 C.F.R. § 201.66(h) would preempt any state or local requirement for OTC drug labeling format or content ". . . that is different from, or in addition to, that required by **FDA."** Such national uniformity is important for all OTC drug or cosmetic-drug products, whether or not subject to the specific terms of this labeling regulation.

OTC drugs in general and cosmetic-drugs specifically are almost universally manufactured for sale throughout the United States. The same label appears on the product throughout the country. Congress has provided an appropriate framework for regulating the safety and efficacy of these products in the Federal Food, Drug, and Cosmetic Act and has given FDA the authority to regulate these products.

Over and over again, **FDA's** authority has proven to be effective to protect American consumers throughout the country. It provides a comprehensive regulatory

framework to ensure that all OTC drug products are safe and effective, that these products are labeled in a manner that is not misleading, and that provides the consumer with the information necessary to use the product safely to obtain the intended drug benefit.

Despite this strong federal regulatory framework, periodically states have taken actions that were in addition to or inconsistent with existing FDA standards. Where appropriate, FDA has taken action to preempt those requirements by regulation to ensure that a single national standard prevailed for OTC drugs.[35] CTFA strongly believes that the action FDA has proposed in this regulation to ensure national uniformity also is appropriate and is critical to ensuring that FDA's authority over the safety of drugs in the United States is not undermined by inconsistent action at the state or local level.

A single example of a current law that has had the effect of undermining FDA's national regulatory scheme is sufficient to illustrate the compelling need for national uniformity. In 1986, the Safe Drinking Water and Toxic Enforcement Act was passed through a voter initiative in California. Otherwise known as "Proposition 65," this law allows the state to identify chemicals "known" to cause cancer or reproductive toxicity. Under the terms of the law, a manufacturer causing an exposure to any product containing these chemicals as an ingredient or contaminant in any amount is required to warn consumers unless the manufacturer can prove that there is not a significant risk to humans from that exposure. For some chemicals, the state has set exposure levels that trigger warning requirements but these levels frequently are not consistent with federal standards.

Further increasing the chances for inconsistency with federal standards for FDA regulated products, Proposition 65 is not enforced by a state agency with scientific expertise. It is enforced in the courts by state law enforcement officials, and, if they fail to act, private citizens. In short, anyone with any agenda can bring a Proposition 65 enforcement suit, publicly challenging the safety of a product, and can argue to a judge or jury that a product requires a warning if it contains a chemical "known to the state of

California" to cause cancer or reproductive toxicity. Neither the plaintiff nor the court is required to consider FDA or other federal standards for safe exposure in making a decision.

Although the Commissioner of FDA and numerous other current and former public health officials successfully argued for an exemption from Proposition 65 requirements for FDA-regulated products, that exemption subsequently was repealed as a result of a court settlement between the state of California and environmental groups in 1993. FDA action to restore national labeling uniformity for OTC drugs is appropriate and necessary.

Although efforts to enact Proposition 65-type laws in other states have, to date, been overtaken by common sense, there is a continuing danger that other states could take similar action that also would be inconsistent with federal law. Completing the nightmare for consumers and industry, these other states may adopt standards that are inconsistent both with the federal government and with California law, leading to a scenario where products will bear different warnings in different states and no warnings in other states. This chaos and confusion can be avoided by the adoption of proposed § 201.66(h). The preemption exemption procedure in proposed § 201.66(i) appropriately allows for an exemption from preemption where state or local action is necessary due to some compelling local interest.

CTFA fully supports FDA's proposal to restore national uniformity to OTC drug labeling, and urges FDA to consider similar action to ensure national uniformity for all FDA-regulated products.

VIII. CTFA's Response to Specific Requests for Comments.

Throughout the preamble to the proposal, FDA calls for comments on numerous issues. CTFA responds to applicable requests as follows:

A. Separation Of Active Ingredient Labeling From Inactive Ingredient Labeling Is Inappropriate (62 *Fed. Reg.* at 9035).

FDA is proposing that if inactive ingredient labeling is either required or voluntarily provided, it be separated from active ingredient labeling and placed after all other required information. As FDA's own Example 6 in the proposal shows, this would put inactive ingredient information at the bottom of the required label, causing substantial harm to cosmetic-drug products. CTFA strongly objects to this aspect of the proposal, and believes it further demonstrates the incompatibility of this proposal with cosmetic-drugs.

Presently, cosmetic-drug products are required to list both active and inactive ingredients.[36] Of critical importance, FDA requires that inactive ingredients be listed in descending order of predominance in the product. OTC drug products presently are required to list active ingredients only. The NDMA policy reflected in the Guidelines for the Disclosure of Inactive Ingredients provides for the voluntary disclosure of inactive ingredients in alphabetical order.

As discussed above, avoidance of certain cosmetic/inactive ingredients that may cause allergic reactions is perhaps the single most important use of required information on a cosmetic label. Throughout the rulemaking on ingredient labeling for cosmetics, conducted nearly 25 years ago, FDA recognized the important health benefit to consumers provided by such information.[37] To physically separate this information from active ingredient information, thereby diminishing the possibility that consumers will find and use such information is wholly unjustified, especially since there is no basis for this entire proposal as it relates to cosmetic-drug products.

Further, NDMA is suggesting to FDA that listing inactive ingredients in alphabetical order should be allowed for those OTC drug companies that voluntarily choose to list this information. This whole issue further highlights the fact that cosmetic-drugs should not be required to utilize this new format which under NDMA's proposal would be inconsistent with the legal requirement for listing cosmetic inactive ingredients under FDA cosmetic labeling regulations.[38] The preamble establishes that FDA has not recognized the importance of inactive ingredient labeling for cosmetic-drug products; nor the impact on consumers if the information is separated; nor whether it

makes sense to have one class of products list inactive ingredients in alphabetical order.

For cosmetic-drug products, consumers are best served by the present ingredient labeling requirements. There is no evidence cited by FDA that any problems have resulted from the existing labeling of cosmetic-drugs, and there is a significant danger that the FDA labeling proposal could lead to unintended, negative results for consumers using these products.

B. Quantitative Declaration Of Active Ingredients Is Unnecessary For Cosmetic-Drug Products (62 *Fed. Reg.* at 9032).

FDA has proposed that the quantity of each active ingredient appear prominently on the labeling. FDA states, "[I]n order for consumers to distinguish among products within a pharmacological category, and select the appropriate product to meet their needs, such information is essential".[39] In reading FDA's preamble, it is perfectly understandable why for certain Rx-OTC switch product categories or cough/cold products such information fulfills a public health need. There is, however, nothing in the record to establish the need for such quantitative active ingredient labeling for cosmetic-drug products. In fact, there is no such need.

Sunscreen products show why such a proposal, applied to cosmetic-drug products, would be highly misleading to consumers. The efficacy of sunscreen active ingredients is not directly related to the amount of active sunscreen ingredient present in the formulation. SPF is not dependent only on the choice of sunscreen actives present. In many of today's formulations, synergisms between sunscreens and the vehicle occur in the intact formulation. This phenomenon has been demonstrated by Meadows[40], who has shown that there are combinations of actives at low levels that yield higher SPF values than those found for the same actives at their maximum concentrations. Furthermore, as can be seen in the publication by Sayre[4] „ the components of the vehicle can play an important role in achieving the final product SPF value. Such effects may not be apparent from merely measuring the individual sunscreen active ingredients in the vehicle formulation.

There already exists an excellent source of information on the labeling of sunscreen to distinguish between products: SPF labeling. Therefore, far from being "essential", such information would lead consumers to make inappropriate, and misleading, comparisons. Once again, this aspect of the proposal establishes that the application of this proposal to cosmetic-drug products with no dosage limitation was neither carefully considered by FDA nor justified in fact.

C. The Proposed Labeling Requirements Should Not Apply To Inner Containers (62 *Fed. Reg.* at 9037).

FDA has solicited comment on whether certain elements of the new format should be required on the immediate container of an OTC product where that product is **sold** with an outer container. As proposed by the agency, "the new format will not apply to the product's immediate container, unless the product is sold without an outer package or wrapper."[42] Accordingly, under the terms of the proposal, where a product is sold with an outer package or wrapper, only the outer package or wrapper, not the inner container, need comply with the new OTC label requirements. CTFA supports this aspect of the proposal for those OTC drug products subject to the new labeling requirements.

As FDA noted in the preamble, if the agency were "to require the proposed labeling format, and the information that would be presented within that format, to appear on the immediate container of all marketed OTC drug products, many products as currently marketed could not conform with the proposed requirements."[43] CTFA shares the agency's concern. If such labeling requirements were imposed on inner containers, many OTC products would require larger containers to accommodate the required labeling. As discussed above in Section VI.B., CTFA has serious concerns regarding the environmental effect of any proposal that would require the industry to increase packaging -- particularly when such a requirement provides no corresponding benefit. Where a product has an outer container, consumer purchase decisions will be made based on the information contained on the labeling of the outer container. The additional benefit provided by repeating such information on the inner packaging would be minimal. Moreover, federal and state slack-fill requirements likely would prohibit any

such increases in product container size. Accordingly, CTFA would strongly object to any proposal that would require that FDA's proposed labeling be repeated on inner packaging.

D. No Minimum Type Size Should Be Established (62 *Fed. Reg.* at 9036).

FDA solicited comment on a variety of issues relating to type size. First, the agency proposes that most label information not required on the PDP be displayed in 6 point type and requests comment on this issue.[44] Second, the agency "requests comment on whether FDA should establish minimum type size requirements for the principal display panel."[45] Third, the agency requests "comment on whether to require that a package insert, or similar accompanying material, printed in a larger point size (such as 10 point type), be included with every OTC drug product."[46] Fourth, the agency requests comment on the use of alternative packaging designs to increase available label space.[47]

While CTFA agrees that label type must be conspicuous and readable, CTFA opposes the imposition of a minimum type size requirement. As FDA is aware, there are many factors other than type size (e.g., highlighting and layout) that affect label readability. Type size that is smaller than 6 point is readable, particularly when highlighted and laid out appropriately.[48] Therefore, imposing an arbitrary numerical restriction on type size does not ensure the most conspicuous, readable labels. Manufacturers should be allowed flexibility to design the most conspicuous and readable label appropriate for a given product. Accordingly, while FDA may wish to recommend the use of 6 point type, the agency should not require it.

Moreover, FDA's currently proposed minimum 6 point type requirement is unworkable for the simple fact that it cannot be accommodated on the label of existing packages. Our members have indicated to us that, given current package and label configurations, not all required information can be accommodated if it must appear in 6 point type.[49] This, of course, leaves manufacturers in the untenable position of either needlessly increasing package size, which raises environmental concerns, or simply

eliminating smaller products, the packaging of which could not accommodate all required information in six-point type.

CTFA also opposes the imposition of a 6 point minimum type requirement because there is no evidence that it would produce benefits proportional to its attendant costs. FDA has not provided an adequate basis in the record to justify the sweeping label changes required by the imposition of a minimum 6 point type size requirement. For the same reasons, CTFA also would oppose any FDA proposal to require that information that appears on the PDP appear in 6 point type.

The third issue FDA seeks comment on with regard to type size is the use of package inserts. CTFA vigorously opposes the idea of requiring inclusion of package inserts appearing in larger type in all OTC drug products. First, many OTC products currently are sold without outer packaging. A requirement that all OTC products be accompanied by a package insert would necessitate the development of outer packaging in which to enclose a patient package insert for those products that do not already have outer packaging. This raises significant cost and environmental issues. Once again, FDA has not provided any evidence that such package inserts are needed or even that they would be beneficial. In light of the lack of any evidence of their benefit, it is unthinkable that FDA would impose such a costly solution on manufacturers.

Similarly, FDA also proposes that manufacturers develop alternative package designs in order to increase label space to accommodate the proposed 6 point type requirement. Once again, in light of the fact that FDA has not provided any evidence that such designs might be beneficial yet are known to be quite costly, CTFA would strongly oppose any FDA proposal to require them.

IX. The Cost Of Relabeling Is Prohibitive And Creates A Disincentive To The Manufacture Of Cosmetic-Drug Products.

CTFA conducted a survey of its members to estimate the costs associated with label development and changes associated with labeling redesign under the proposed

rule. This survey assessed the total cost and time involved based on a minor and major label change. Several factors were considered to determine the costs of relabeling including personnel, vendors, and plant scrap. SKU distinctions were also based on color categories.

CTFA survey data indicate that assuming it were feasible to comply with new FDA labeling requirements, the average incremental cost to redesign each cosmetic-drug product label will be $7,900.00 (no scrap) and $11,300.00 (with scrap) per SKU. This data indicates that the cost is significantly higher than the agency's estimate of $1,500.00 per SKU.[50] Based on the results of this survey, the cosmetic-drug industry will incur substantial costs to relabel according to the new format.

Based on these estimated costs, the agency's proposed rule creates a disincentive for industry to manufacture and market cosmetic-drug products and/or an unreasonable and unjustified inflationary factor in the cost of cosmetic-drugs to consumers. Manufacturers have worked diligently to incorporate drug benefits into new and existing cosmetic products. Consumer demand for these products indicates a strong desire, where possible, to seek cosmetic and drug benefits in a single product. The expense and lack of flexibility to accommodate the special needs of this class of products (i.e., both cosmetic and drug labeling), may prove a barrier to further development of these products, and could lead to the reduced availability of cosmetic products that provide preventive drug benefits as well. The American public could lose a valuable health benefit, such as the ready availability of sunscreen protection in many different forms on the yet-to-be proven basis that cosmetic-drug products which already satisfy existing regulatory requirements must be reformatted to meet a new, untested label format.

As thoroughly discussed throughout this document, cosmetic-drugs do not present the safety and consumer confusion issues that FDA puts forth as the reasons for the new format. Thus, there is no real benefit to requiring a new label format for

cosmetic drugs as described herein. Absent some quantifiable benefits, the significant costs to make these label format changes are absolutely unjustified.

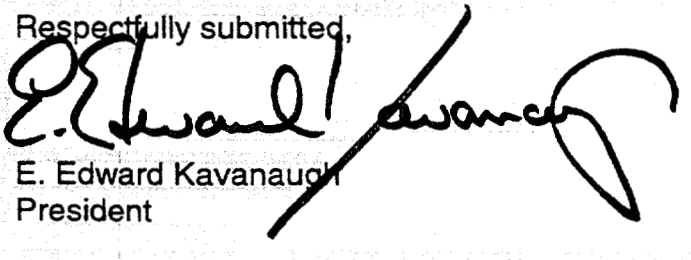
CONCLUSION

CTFA strongly urges FDA, after careful analysis of its stated rationale and its obligations under the Administrative Procedure Act, to exempt cosmetic-drug products with no dosage limitation from this proposed OTC drug labeling rule, if finalized. [51] These cosmetic-drugs should remain labeled as presently required. Further, there are compelling arguments for FDA to grant a small package exemption for cosmetic-drugs.

Cosmetic-drug products with no dosage limitation have been properly labeled and used safely and effectively for decades. To the extent that FDA has created an administrative record involving the changing patterns of OTC drug use, that record is totally devoid of any discussion *of* concern for cosmetic-drug products. The present FDA labeling requirements for both OTC drugs and cosmetics should continue to apply to these product categories. FDA's proposal bears no recognition that these products, unlike other OTC drugs, must meet both sets of requirements and that there is other highly valuable consumer information that would get lost in a newly mandated OTC drug labeling format focused on very different products.

FDA's proposal, as applied to cosmetic-drugs with no dosage limitation, is costly, without justification, and quite likely to have an impact that is directly contrary to the public health goals that FDA seeks to uphold.

Respectfully submitted,



E. Edward Kavanaugh
President

1. 62 *Fed. Reg.* 9024, 9027 (1997) (to be codified at 21 C.F.R. pts. 201, 330 and 358) (proposed Feb. 27, 1997).
2. *Id.*
3. *Id.* at 9028.
4. *Id.* at 9027-28.
5. *Id.* at 9027.
6. Contributing to the wide margins of safety of cosmetic-drugs is the fact that, unlike many other OTC drugs -- where the intended target tissue (i.e., the site of therapeutic benefit) is *distal* to the site of application (and therefore systemic exposure is a necessary pre-requisite to delivery to the target tissue) -- the site of application of all cosmetic-drugs *is* the intended target tissue. Systemic exposure tends to be minimized following use of topical cosmetic-drug products because of a combination of the barrier function of the stratum corneum and because many products (e.g., sunscreens, antiperspirant/deodorants and skin protectant products) are designed so that active ingredients remain on the skin (or in the skin) for maximum efficacy. Similarly, for products such as anti-caries toothpastes, and anti-dandruff shampoos, systemic exposure is minimized because typical product usage involves brief and discontinuous exposure (followed by rinsing).
7. In determining whether a drug active ingredient is appropriately afforded OTC status, FDA is required by statute to consider (i) toxicity and "other potentiality for harmful effect" (e.g., potential for abuse, potential to induce drug tolerance, etc.) and (ii) method of use, or collateral measures necessary to use. 21 U.S.C. § 353(b)(1)(B). The legislative history of the 1951 Durham-Humphrey Amendment (which codified the distinction between prescription and OTC drugs) suggests that Congress intended the second consideration to have the broadest possible scope. *See* Peter Barton Hutt, *A Legal Framework for Future Decisions on Transferring Drugs from Prescription to Nonprescription Status*, 37 Food Drug Cosmetic Law Journal 427 (1982) (scope of consideration to encompass all aspects of circumstances under which drug is used, including broad questions of social policy).
8. The 1995 (the most recent year for which published data is available) *Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System* contains data demonstrating that cosmetics/personal care products (including cosmetic-drugs) are the safest of all nonpharmaceutical products in terms of reported exposures resulting in human poisoning.
9. 21 U.S.C. § 321(g)(1)(B).
10. 21 U.S.C. § 321(i)(1).
11. 21 U.S.C. § 321(g)(1)(C). Products which come within the cosmetic *and* drug definitions are regulated (and must be labeled) as *both* cosmetics *and* drugs. 21 U.S.C. § 321 (i) and (g) respectively. For example skin care products such as moisturizers are examples of typical cosmetic products; however, adding a sunscreen active ingredient *and* making an SPF protection claim makes the product both a cosmetic *and* a drug.
12. 62 *Fed. Reg.* 9024, 9027.
13. *Id.* at 9027-28.
14. *Id.* at 9028.
15. *Id.*
16. *Id.* at 9045.
17. *Id.* at 9028.

18. The 1995 American Association of Poison Control Centers Toxic Exposure Surveillance System, a database which compiles poisoning information from 69 regional poison centers throughout the United States, lists only 69 "major outcomes" and 3 deaths for exposure to **all** cosmetic/personal care products which include toothpaste and mouthwashes with fluoride, and suntan/sunscreen products, as well as shampoos, soaps, and deodorants. By contrast, for products containing an analgesic - extremely safe and commonly used as a single active ingredient, 501 major outcomes and 55 deaths were reported for the same time period for one common analgesic, and 164 major outcomes and 48 deaths for another - Each is significantly higher than all cosmetic and personal care products.

19. 62 *Fed. Reg.* 9024, 9028.

20. *But see*, Dorland's Medical Dictionary 504 (28th Edition 1994).

21. 21 C.F.R. §§ 201, 328, 330, 369, and 701. For example, all OTC drug products must have a statement of identity indicating the established name of the drug, as well as language indicating the uses of the product. They must provide adequate directions for use and other information including required monograph and other warning statements.

22. 21 C.F.R. §§ 701.3(a) and (d).

23. Proposed 21 C.F.R. § 201.66(c). ***See also* 62 *Fed. Reg.* 9024,9035.**

24. 21 C.F.R. § 740.11.

25. Manufacturers also have a vested legal interest in preserving adequate label space for additional copy. For example, to acknowledge a registered trademark, e.g., that "Parsol® is a registered trademark of Givaudan-Roure Corporation," for sunscreen products.

26. 21 U.S.C. § 352(c).

27. 54 *Fed. Reg.* 13490, 13495 (April 13, 1989) (label separation policy).

28. Skin Bleaching Drug Products for Over-the-Counter Human Use: Tentative Final Monograph, 47 *Fed. Reg.* 39108, 39115 (September 3, 1972).

29. *See*, e.g., Topical Acne Drug Products for Over-the-Counter Human Use: Tentative Final Monograph, 50 *Fed. Reg.* 2172, 2177 (January 15, 1985).

30. Page 1 of EPA June 1997 "Pollution Prevention 1997 - A National Progress Report, Executive Summary: "This common sense understanding is reflected in the environmental management hierarchy of the Pollution Prevention Act of 1990, in which Congress established as national policy that: Pollution should be prevented or reduced at the source whenever feasible."

31. Letter from John E. Bailey, Ph.D, Acting Director, Office of Cosmetics and Colors, to Thomas J. Donegan, Jr., Vice President and General Counsel, CTFA (March 24, 1993).

32. Canadian Food and Drugs Regulations, §C.10.001(a)

33. "A Guide to Canadian Regulatory Requirements," The Canadian Cosmetic, Toiletry, and Fragrance Association, Ontario, Canada (May 13, 1997), pages 1-20

34. E.C Cosmetics Directive 76/768/EEL, as amended, Annex I, Illustrative List by Category of Cosmetic Products.

35. 51 *Fed. Reg.* 8180 (March 7, 1986); 21 C.F.R. §201.314(h) (Reye Sundrome warning) 47 *Fed. Reg.* 54760 (Dec. 3, 1982); 21 C.F.R. § 201.63 (pregnancy-nursing warning); 47 *Fed. Reg.* 50442 (Nov. 5, 1982); 21 C.F.R. §211.132 (tamper-resistant OTC drug packaging).

36. 21 C.F.R. § 701.3.

37. *See* e.g., 38 *Fed. Reg.* 3523 (February 7, 1973).

38. 21 C.F.R. § 701.3(a).

39. 62 *Fed. Reg.* at 9032

40. Meadows T. The effect of various sunscreen combinations on a product's SPF value. J. Soc. Cosmet. Chem. 41, 141-146, 1990.

41. Sayre RM, Sunlight risk and how sunscreens work. Cosmetics and Toiletries 107, 105-112,1992.

42. *62 Fed. Reg. at* **9037.**

43. *Id.*

44. *62* ***fed. Reg.*** *at 9036.*

45. *Id.*

46. *Id.*

47. *Id.*

48. Indeed, in the preamble to the final rule on dietary supplement labeling FDA relied on NDMA's Label Readability Guidelines for OTC Drugs (based on NDMA studies of visual acuity and demographics) to support the use of a type size of 4.5 for certain packages. 62 *Fed. Reg.* 49826, 49839 (September 23, 1997). FDA's recognition of the readability of a 4.5 type size in that context is fully consistent with our position that type size that is smaller than 6 point is readable.

49. Currently, 1/16 inch and 1/32 inch type are required to be used for ingredient labeling on cosmetic-drugs. This type size would not satisfy a 6 point minimum type requirement.

50. 62 *Fed. Reg. 9047*

51. CTFA's specific request is for an exemption for "any cosmetic drug product that does not bear dosage limitation." Although many of the arguments presented in this comment apply equally to all cosmetic-drugs, we believe the "no dosage limit" qualification on our request responds to any possible concern that FDA could have about current OTC drug labeling.